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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,488	11/20/2003	Richard W. Armentrout	850136.422	3667

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EXAMINER	
FERNANDEZ, SUSAN EMILY	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,488	ARMENTROUT, RICHARD W.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2008, has been entered.

Claims 16 and 17 are pending and examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitra et al. (Nucleic Acids Research. 1999. 27(24)e34: i-vi, listed on IDS) in view of Cole (BioTechniques. April 1999. 26: 748-756).

Mitra et al. discloses the *in situ* amplification of DNA, wherein "...acrylamide is polymerized in a solution containing standard polymerase chain reaction (PCR) reagents and a very low concentration of linear DNA template" (page i, first column, last paragraph). The resulting gel is poured in a glass microscope slide which is then thermal cycled, allowing the amplification reaction to occur (page i, second column, first paragraph). Note that the polymerase chain reaction reagents consist of Taq (DNA polymerase) dNTPs, and template

DNA (target nucleic acid) (page ii, first column, last full paragraph). Clearly Mitra et al. teaches a nucleic acid amplification reaction mixture comprising of DNA polymerase, dNTPs, and target nucleic acid, though it also comprises acrylamide.

Mitra et al. differs from the claimed invention in that the nucleic acid amplification reaction mixture does not comprise of gellan in water wherein the concentration of gellan is above 0.005 wt% based on the weight of water.

Cole discloses gellan electrophoresis gels for the separation and isolation of DNA (abstract). The gellan electrophoresis gels of concentrations as low as 0.03% were prepared, but a typical gellan electrophoresis gel concentration was 0.1% (page 750, second column).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have substituted the acrylamide of the nucleic acid amplification reaction mixture taught in Mitra et al. with gellan gel, such as the gellan gels taught in Cole. One of ordinary skill in the art would have been motivated to do this since gellan gel serves as an alternative gel material which allows for easy recovery of DNA (Cole, page 756, last paragraph), requires low concentrations for gel formation, and has reversibility (Cole, page 749, first column, second paragraph).

Note that in instant claim 17, the recitation of "template-dependent nucleic acid amplification is of enhanced sensitivity" indicates the intended use of the composition. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed January 28, 2008, have been fully considered but they are not persuasive. In regards to the applicant's assertion that the gellan sequesters magnesium ions which are necessary for the nucleic acid amplification reaction, it is noted that page 5, lines 25-27 in the specification does not speak to the formed gel. It is noted that page 5, lines 25-27 indicates that "..the intact gellan polymer sequesters Mg^{2+} as cross-linking ions **for gel formation**" (emphasis added). Clearly magnesium sequestration is not in reference to the formed gellan gel, but to gellan gel formation. For support, the specification points to Doner et al. (Biotechnology Techniques. 1991. 5(1): 25-28). However, it is respectfully noted that Doner et al. does not speak of magnesium sequestration by gellan. Thus, it is not clear to what degree magnesium ions are sequestered by gellan, and moreover it is not clear to what degree magnesium becomes unavailable for the nucleic acid amplification reaction.

With respect to the applicant's assertion that Cole teaches that divalent cations weaken gellan gels, it is noted that Cole instead teaches that the detrimental effects of divalent cations on gellan gum occurs only when not all of the gellan gum particles are in solution (page 750, first column, last paragraph). Clearly there is no teaching away from the use of gellan in a nucleic acid amplification reaction mixture. Thus, the claims must be rejected over the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef